Study on psychological effects and moral implications of a continued pregnancy of a child identified as carrier of Huntington's disease

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1. Investigating the psychological motives, moral considerations and experiences of couples who decided to not terminate an affected pregnancy2. Insight into the current individual psychological condition and relationship of couples with regard to...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Family issues
Study type	Observational non invasive

Summary

ID

NL-OMON41170

Source
ToetsingOnline

Brief title
implications of continued pregnancy with Huntington's disease

Condition

- Family issues

Synonym
hereditary brain disorder, neurogenetic disorder

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: continued pregnancy, Huntington's disease, prenatal testing, psychology

Outcome measures

Primary outcome

Zijn er individuele psychologische en morele conflicten bij ouders als gevolg

van de beslissing de zwangerschap niet af te laten breken?

2. Zijn er psychologische en morele conflicten in de relatie gerelateerd aan de

beslissing de zwangerschap niet af te breken?

3. Hoe handelen ouders jegens hun kinderen wat betreft het informeren over hun

dragerschap voor HD?

Secondary outcome

NOT APPROPRIATE

Study description

Background summary

Huntington's disease (HD) is an autosomal dominant hereditary neurodegenerative disorder with onset in adulthood. HD has a profound impact on the family en relatives who know that thwey may develop the disease in the future. Individuals at risk who do not wish to pass the causative mutation on to their offspring have the option of prenatal diagnosis (PD). According to international guidelines couples opting for PD are expected to terminate teh pregnancy after positive results (the unborn has been identified as a mutation carrier). Since the availability of PD 12 Dutch couples have decided not to terminate the pregnancy after positive outcome of PD with the consequence that 12 children are born with the (potential) knowledge of being a carrier with the certainty that they will develop HD in the future. The child is deprived from the option to decide for itself to have presymptomatic testing at adult age. The main question of this study concerns how the decision not to terminate has

affected the parents, psychologically as wel as morally.

Study objective

1. Investigating the psychological motives, moral considerations and experiences of couples who decided to not terminate an affected pregnancy
2. Insight into the current individual psychological condition and relationship of couples with regard to the decision taken
3. Articulation of recommendations for improvement of counselling and decision making regarding application of PD

Study design

Retrospective cohort study using semi-structured interviews and subsequent ethical analysis (desk research)

Research questions:
1. Do couples have any individual and moral conflicts as a result of their decision to not terminate the pregnancy?
2. do couples have any psychological and moral conflicts in the relationship as a result of not terminating the pregnancy?
3. What is the couples* attitude towards their child and other children with regard to informing about carriership of HD?

METHODS

The treating clinical geneticist will inform the couple about the study by phone and subsequently by letter and ask them if the couple is willing to participate and be approached by the researcher. After returning the informed consent form participants will be approached by the researcher for planning the interview and the preferred location. The interview will be held with both partners. Divorced partners will interviewed separately. Interviews will be audio-recorded and transcribed. The researcher has wide experience with couples undergoing presymptomatic and/or prenatal testing.

The interview will address memories of de testing period, the decision making after disclosure of the test results, emotional responses and moral considerations, current emotional reactions and moral individual and relational conflicts, relationship with the child and coping with the knowledge about carriership of the child.

The interview may raise strong emotions in the participants. The researcher is an experienced psychologist and psychotherapist and is able to recognize these emotions and deal with them. On the participants* request the interview can be interrupted at any moment.

After the interview the participants will be debriefed.

Study burden and risks

In this study participants will be interviewed. Potential adverse consequences are not expected but can strong emotions can raise when discussing traumatic experiences, thoughts or feelings. The researcher has broad experience with HD, presymptomatic and prenatal testing and can handle difficult situations. If needed or requested a safety net or additional counselling can be provided, or referral to family physician, psychologist, psychiatrist or neurologist.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

couples who have continued a pregnancy with identified Huntington's disease

Exclusion criteria

Couples who have objected against using their data
Incompetent, e.g. as a result of symptoms of Huntington's disease, the healthy partner will be asked to participate in the interview

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	25-04-2014
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL47939.058.14